

Remarks

Claims 35-43, 45-46, and 51-59 are pending. Claims 35-42 are withdrawn. Claims 43, 46, and 51 have been amended. Support for the amendments to claim 43 can be found on page 3, lines 23-26, on page 33 line 17 to page 36, line 17; and on page 21, lines 5-21; on page 7, line 29 to page 8, line 6; on page 19, lines 1-11. Support for the amendment to claim 46 can be found on page 5, lines 4-5; page 8, line 9; and page 25, lines 5-6. Support for the amendment to claim 51 can be found in original claims 9-13, on page 7, line 32; and on page 15, line 16.

Applicants would like to thank the Examiner for the telephonic interview of September 3, 2008. The information provided was very helpful and applicants hope that the Examiner's suggestions are reflected in the comments and amendments found herein. An Interview Summary is attached herewith.

The Office Action of June 11, 2008 stated that claims 60-79 were a distinct invention and therefore were not examined. Applicants respectfully traverse. In an effort to expedite prosecution, claims 60-79 have been canceled. It is noted, however, that claim 43 has been amended to substantially resemble canceled claim 72. It is applicants' assertion that this amendment of claim 43 is not drawn to a materially distinct method when compared to original claim 43. The Office Action states that claim 72 "differs at least in objectives, method steps, response variables, and criteria for success. Furthermore, there is nothing of record to show them to be obvious variants."

Applicants disagree on the following grounds. First of all, claim 43, as amended, does not differ in objective from the original claim 43, which was to correlate a cancer with erbB-3 expression levels. While the original claim was drawn to a method of classifying a cancer by determining the expression level of erbB-3, the amended claim is drawn to a method of determining expression level of erbB-3. It is noted that determining expression level of erbB-3 would have been a necessary component of a method of classifying a cancer. Therefore, it is applicants' assertion that the claim as amended recites essentially the same process as a method of classifying a cancer, but simply does not recite the additional step of comparing the level of expression to a control for the method of classification, as found in the original claim. The

second criterion offered, that the method steps are not the same in claim 43 and claim 72, is also not correct. The method steps are nearly identical, as step a) in both the amended and the original claim recites measuring the level of expression of erbB-3, and step b) is amended only slightly from comparing the level of expression of the erbB-3 to a control to simply determining the level of erbB-3 (without comparing it to a control). Therefore, the method steps are essentially identical. The third criterion is response variables, which is interpreted to mean the response that results from carrying out the method steps. The response (i.e., end result) in both the original and amended claim 43 is identical, as the level of expression of erbB-3 is determined in both. The fourth criterion is the “criteria for success”. In the case of the original and the amended claim, the criteria for success is based upon the expression of erbB-3, as its detection is paramount in both the original and the amended claim. Without the detection of expression of erbB-3, neither the original or the amended claim has criteria for success. And lastly, the Office Action states that there is nothing in the record to show that the original claim and the amended claim are obvious variants of one another. Applicants assert, however, that this is not the case, and that determining level expression of erbB-3 is an obvious variant of classifying a cancer by determining expression of erbB-3 in a sample. Again, the only difference is that in the amended claim, the level of expression is not correlated with a control. This would clearly be an obvious variant.

According to the MPEP 802.01, related inventions are distinct if the inventions as claimed are not connected in at least one of design, operation, or effect (e.g., can be made by, or used in, a materially different process) and wherein at least one invention is patentable (novel and nonobvious) over the other (though they may each be unpatentable over the prior art). In this case, the original and amended claim cannot be considered to be distinct because a) they are connected in that they have the same effect (determining expression of erbB-3), and b) they would not have been considered to be patentable over each other, as all of the steps in the amended claim would have been used in the original claim, and the end result (determining expression of erbB-3) would have been the same. Applicants therefore urge that the newly amended claim 43 is an obvious variant of original claim 43, and for this reason newly amended claim 43 should be examined.

Priority

The Office Action states that, “The preliminary amendment is drawn to a method of classifying a cancer as being correlated with expression of an erbB-3 gene. However, the preliminary amendment as filed contains subject matter not otherwise included in the specification and drawings of the application since neither the term ‘classifying’ nor the concept of classifying a cancer as being correlated with expression of an erbB-3 gene is found in the specification as originally filed.” Applicants respectfully disagree. Specifically, the oldest priority document, now U.S. Patent 5,183,884, teaches the concept of the classification of cancer using erbB-3 in col. 2, lines 2-19; col. 2, lines 57-62; col. 8, lines 35-46; col. 10, line 66 to col. 11 line 10; col. 11, lines 11-16; and col. 15, line 6 to col. 16, line 22. Therefore, it is clearly demonstrated that the concept of classifying a cancer is taught. However, in an effort to expedite prosecution, the claims have been amended to recite a method of determining expression of erbB-3, which is also clearly taught in original priority document U.S. Patent 5,183,884, such as in col. 4, lines 38-54; col. 15, line 6-col. 16, line 22; and col. 11, lines 11-16. Therefore, applicants respectfully request that the present claims be given priority to December 1, 1989.

Specification

The Office Action states that the application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences but that there are no SEQ ID NOs identified with the sequences disclosed in Figures 3 and 4. Applicants thank the Examiner for pointing this out, and herewith submit a sequence listing in compliance with 37 CFR 1.8821 (a)(1) and (a)(2). Applicants therefore respectfully request withdrawal of this objection.

Claim Rejections – 35 USC § 112, First Paragraph

Claims 43-46 and 51-59 are rejected under 35 U.S.C. 112, first paragraph, for allegedly failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Office Action asserts that the claims are drawn to a method of classifying a cancer as being correlated with a greater amount of expression of an erbB-3 gene as compared to a control, but that the specification does not provide an adequate written description of an erbB-3 gene. Applicants respectfully traverse, since one of skill in the art would readily have been apprised what an erbB-3 gene was, and would have been able to identify an erbB-3 gene based on the disclosure of the gene in the specification. However, in an effort to expedite prosecution, applicants have amended the claims so that an erbB-3 gene is no longer recited. Applicants therefore respectfully request withdrawal of this rejection.

Claim Rejections – 35 USC § 102

Claims 43-46, 51, 52, 55, and 58 were rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Lemoine et al (Br J Cancer, December 1992, 66:1116-1121), as evidenced by Prigent et al (Oncogene, July 1992, 7:1273-1278). Applicants respectfully traverse this rejection as it applies to amended claim 43 and those claims that depend there from. As pointed out above, the claims as amended have priority to U.S. Patent 5,183,884, which has a filing date of December 1, 1989. Therefore, the art of Lemoine from 1992 is not properly applied. Applicants therefore respectfully request withdrawal of this rejection.

Claims 43-45, 51-53, 55, 57, and 58 were rejected under 35 U.S.C. 102(b) as being allegedly being anticipated by Rajkumar et al (J of Pathology, 1993, 170:271-278), as evidenced by EP 0 444 961 A1, Plowman et al, published September 4, 1991. Applicants respectfully traverse this rejection as it applies to amended claim 43 and those claims that depend therefrom. As pointed out above, the claims as amended have priority to U.S. Patent 5,183,884, which has a filing date of December 1, 1989. Therefore, the art of Rajkumar et al. (1993) is not properly applied. Applicants therefore respectfully request withdrawal of this rejection.

Claim Rejections – 35 USC § 103

Claims 43-45, 51, 52, 55, and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prigent et al (Oncogene, July 1992, 7:1273-1278) in view of Lemoine et al II (Gut, October 1992, 33:1297-1300).

Applicants respectfully traverse this rejection as it applies to amended claim 43 and those claims that depend there from. As pointed out above, the claims as amended have priority to U.S. Patent 5,183,884, which has a filing date of December 1, 1989. Therefore, the art of Prigent et al. (1992) is not properly applied. Applicants therefore respectfully request withdrawal of this rejection.

Conclusion

It is believed that the application is now in condition for immediate allowance. Pursuant to the above amendments and remarks, reconsideration and allowance of the pending application is believed to be warranted. The Examiner is invited and encouraged to directly contact the undersigned if such contact may enhance the efficient prosecution of this application to issue.

A credit card payment is being submitted via EFS Web in the amount of 65.00, representing the fee for a large entity under 37 C.F.R. § 1.17(a)(1), and a Request for Extension of Time is enclosed. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

/Janell T. Cleveland/

Janell T. Cleveland
Registration No. 53,848

BALLARD SPAHR ANDREWS & INGERSOLL, LLP
Customer Number 36339
(678) 420-9300
(678) 420-9301 (fax)

ATTORNEY DOCKET NO. 14014.0306U2
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